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October 21, 2004

VIA FEDERAL EXPRESS

Division of Dockets Management
Food and Drug Administration
Room 1061 (HFA-305)
5630 Fishers Lane
Rockville, MD, 20852

Re: Draft Guidance for Industry, "Help-Seeking" and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms [Docket No. 2004D-0042]

Dear Sir/Madam:

This letter is in response to FDA's request for comment on the above referenced draft guidance. Specifically, this letter provides suggestions to assist in the determination of whether two communications are "perceptually distinct", and addresses "close physical or temporal proximity" and how "proximity could be best considered for two communications that are not perceptually distinct if they were presented in the same publication". Although we know of no specific data on either of these terms, we have given thought to methodologies that could be used to obtain such information. If FDA were to conduct this or similar research described below it may help to establish data that could be used to define the noted terms.

Overall Objectives

The objectives are to: 1) define the term "close proximity" as it pertains to time (i.e., at what specific time in minutes or hours do consumers no longer make an association between the unbranded/branded ads), and 2) determine how "close proximity" could be defined when two communications are not perceptually distinct within the same medium (i.e. magazines, other forms of print, etc.).

Proposed Methodology-TV

Given the overall interactive nature of the objectives, a methodology that closely simulates "real world" conditions is recommended. In the case of direct-to-consumer television broadcast advertisements (DTC), videotapes of ½ or 1 hour TV programs could be created which contain both embedded "typical" non-pharmaceutical commercials and unbranded as well as branded

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DTC advertisements. For the "Test Group" the time elapsed between the unbranded and branded ads would be varied in specific intervals (e.g., 5 minutes, 15 minutes, 30 minutes, 1 hour, etc.). For baseline purposes, a "Control Group" would be exposed to the same TV program with only a branded campaign. This will allow assessment of the impact of the branded campaign on both recognition as well as likelihood to visit a physician in the absence of unbranded materials. Additionally, it would provide a comparison to overall recognition and response to groups exposed to both the unbranded as well as branded ads. These tapes would then be sent to pre-recruited patients who would be asked to participate in a survey within a 24-hour period.

Assessment of the impact of both campaigns could be based on either pre-determined criteria (i.e., at what time interval do less than 25% of the sample make the connection between the two campaigns) or you can use the final data itself as criteria (i.e., overall means, medians, etc.).

The therapeutic categories to be tested would be at least three of the most heavily advertised unbranded/branded campaigns either currently or recently on air (e.g., statins, allergy medication, etc.)

Sample

Testing should be done with sufferers of each condition. This will ensure potential interest and at least minimal involvement in the campaign. There are several reputable companies that maintain panels of sufferers which will help to reduce the overall cost and not compromise the results significantly (caveat being that panelists are more likely to be active in own healthcare and therefore more likely to be aware of ads and to have taken action; however bias will exist with total sample and should still provide measure for comparison with each group.)

Sample size would be driven by the number of campaigns to be tested. Using the three most heavily advertised unbranded/branded campaigns as noted above, it is recommend that each tape be tested in at least 100 patients in each of the three areas chosen. Assuming three campaigns for assessment among a group of representative patients and assuming that you are testing at least 4 time intervals for each of the three campaigns, you would need a total of 12 cells of 100 patients for a total sample of 1,200 patients.

Areas of Questioning

-Baseline measure of disease state awareness/involvement prior to seeing any advertising
-Baseline measure of brand recall prior to seeing any advertising
-Exposure to unbranded/branded ads
-Assessment of differences in brand recall
-Likelihood to take action
-What actions likely to take

Timing

It is estimated that this study could be conducted in approximately 8-10 weeks.

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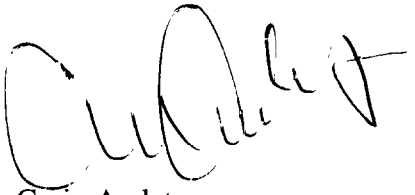
Proposed Methodology - Print Testing

For assessment of print campaigns, a very similar methodology is recommended in regard to sample and areas of questioning. However, the unbranded/branded campaigns would be "tipped-in" to typical magazines and sent to pre-recruited patients. They would then be asked to participate in a follow-up questionnaire within 24 hours.

Should you have any questions, please do not hesitate to contact me at (212) 551-4643 or at the letterhead address.

Sincerely,



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